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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/501,773

07/20/2004

Karl Kolter

53272

8423

26474

7590

04/29/2008

NOVAK DRUCE DELUCA + QUIGG LLP

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EXAMINER

HAIDER, SAIRA BANO

ART UNIT

PAPER NUMBER

1796

MAIL DATE

DELIVERY MODE

04/29/2008

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<p align="center"><b>Advisory Action</b> <b>Before the Filing of an Appeal Brief</b></p>	<p><b>Application No.</b> 10/501,773</p>	<p><b>Applicant(s)</b> KOLTER ET AL.</p>	
	<p><b>Examiner</b> SAIRA HAIDER</p>	<p><b>Art Unit</b> 1796</p>	

**--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

THE REPLY FILED 10 March 2008 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE.

1. ☒ The reply was filed after a final rejection, but prior to or on the same day as filing a Notice of Appeal. To avoid abandonment of this application, applicant must timely file one of the following replies: (1) an amendment, affidavit, or other evidence, which places the application in condition for allowance; (2) a Notice of Appeal (with appeal fee) in compliance with 37 CFR 41.31; or (3) a Request for Continued Examination (RCE) in compliance with 37 CFR 1.114. The reply must be filed within one of the following time periods:

- a) ☒ The period for reply expires 3 months from the mailing date of the final rejection.  
b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.

Examiner Note: If box 1 is checked, check either box (a) or (b). ONLY CHECK BOX (b) WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### NOTICE OF APPEAL

2. ☐ The Notice of Appeal was filed on \_\_\_\_\_. A brief in compliance with 37 CFR 41.37 must be filed within two months of the date of filing the Notice of Appeal (37 CFR 41.37(a)), or any extension thereof (37 CFR 41.37(e)), to avoid dismissal of the appeal. Since a Notice of Appeal has been filed, any reply must be filed within the time period set forth in 37 CFR 41.37(a).

#### AMENDMENTS

3. ☐ The proposed amendment(s) filed after a final rejection, but prior to the date of filing a brief, will not be entered because  
(a) ☐ They raise new issues that would require further consideration and/or search (see NOTE below);  
(b) ☐ They raise the issue of new matter (see NOTE below);  
(c) ☐ They are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or  
(d) ☐ They present additional claims without canceling a corresponding number of finally rejected claims.

NOTE: \_\_\_\_\_. (See 37 CFR 1.116 and 41.33(a)).

4. ☐ The amendments are not in compliance with 37 CFR 1.121. See attached Notice of Non-Compliant Amendment (PTOL-324).  
5. ☐ Applicant's reply has overcome the following rejection(s): \_\_\_\_\_.  
6. ☐ Newly proposed or amended claim(s) \_\_\_\_\_ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).  
7. ☐ For purposes of appeal, the proposed amendment(s): a) ☐ will not be entered, or b) ☐ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.  
The status of the claim(s) is (or will be) as follows:  
Claim(s) allowed: \_\_\_\_\_.  
Claim(s) objected to: \_\_\_\_\_.  
Claim(s) rejected: \_\_\_\_\_.  
Claim(s) withdrawn from consideration: \_\_\_\_\_.

#### AFFIDAVIT OR OTHER EVIDENCE

8. ☐ The affidavit or other evidence filed after a final action, but before or on the date of filing a Notice of Appeal will not be entered because applicant failed to provide a showing of good and sufficient reasons why the affidavit or other evidence is necessary and was not earlier presented. See 37 CFR 1.116(e).  
9. ☐ The affidavit or other evidence filed after the date of filing a Notice of Appeal, but prior to the date of filing a brief, will not be entered because the affidavit or other evidence failed to overcome all rejections under appeal and/or appellant fails to provide a showing a good and sufficient reasons why it is necessary and was not earlier presented. See 37 CFR 41.33(d)(1).  
10. ☐ The affidavit or other evidence is entered. An explanation of the status of the claims after entry is below or attached.

#### REQUEST FOR RECONSIDERATION/OTHER

11. ☒ The request for reconsideration has been considered but does NOT place the application in condition for allowance because:  
See Continuation Sheet.  
12. ☐ Note the attached Information *Disclosure Statement*(s). (PTO/SB/08) Paper No(s). \_\_\_\_\_.  
13. ☐ Other: \_\_\_\_\_.

/Randy Gulakowski/  
Supervisory Patent Examiner, Art Unit 1796

/Saira Haider/  
Examiner, Art Unit 1796

Continuation of 11. does NOT place the application in condition for allowance because: The examiner maintains the position set forth in the Final Office Action. Applicants have essentially submitted the same arguments presented in the Remarks of 10/3/2007. Attention is directed to the Response to Arguments in the Final Office Action mailed on 12/10/2007.

Applicants have argued that the Gotsche fails to anticipate the claimed invention, because in order to arrive at the claimed invention applicants have to select component A, select component B, and then combine components A and B.

In response, in reference to component A, applicant has claimed the genus polyvinyl alcohol-polyether graft copolymer, wherein the reference discloses a graft copolymer genus of polyvinyl alcohol and polyether. The reference forms the copolymer via polymerization of the same components disclosed by applicant in the instant specification. Thus, given that applicant has claimed a genus and the reference has disclosed the genus, the component is anticipated and species selection is not required for component A.

In reference to component B, applicant has claimed an additional polymer with at least one of the claimed functional groups, wherein the reference discloses the claimed additional polymers within a listing of eleven species. It is noted that three of the eleven disclosed species in the prior art read on the species claimed in the instant dependent claims. The limited class of 11 compounds, three of which are claimed (claims 5 and 10) is considered anticipation because one skilled in the art would readily envisage each member of the limited class. Thus, given that the reference clearly names the more than one of the claimed species, component B is anticipated.

Applicants have argued that it is necessary to select portions of the teaching within a reference and combine, thus, applicants argue, the claims are not anticipated by the prior art Gotsche. In response, Gotsche discloses as an alternate embodiment the inclusion of additional polymers (Component B), wherein as per MPEP § 2123, alternate embodiments constitute prior art. Thus, it is clear that the Gotsche reference discloses the claimed invention as arranged in the claim.

In reference to the arguments regarding the 103 rejection of claim 7, it is noted that Gotsche teaches modification of the rate of release and the Castillo reference teaches a specific component utilized to control the rate of release of a film coating on a pharmaceutical presentation. Applicants have argued that Castillo reduces the rate of release, however, the col. 5, lines 29-38 of Castillo indicate that a fully hydrolyzed polymer has a high degree of water resistance and dissolve very slowly at particular temperatures. Thus, it is clear that a fully hydrolyzed polymer will indeed reduce the rate of release, but clearly, it teaches that polymers less than 100% hydrolyzed will result in a increase in the rate of release. The examiner maintains that it would have been obvious to utilize the hydrolyzed PVA of Castillo in order to effectively control the release of the active material after implantation and control the rate of delivery.

Applicant has argued that the instant specification discloses synergistic effects unforeseen by the Gotsche reference. In response, as per MPEP § 2131.01, evidence of secondary considerations, such as unexpected results or commercial success, is irrelevant to 35 U.S.C. 102 rejections and thus cannot overcome a rejection so based. In re Wiggins, 488 F.2d 538, 543, 179 USPQ 421, 425 (CCPA 1973). Thus, the results cannot overcome the 102(b) rejection. Further, the results are insufficient to overcome the 103 rejections because the evidence fails to overcome the basis of the prima facie case of obviousness. The prima facie case of obviousness is based on utilizing hydrolyzed PVA; however applicants' evidence is based on the combination of components A and B. The primary reference anticipates the combination of components A and B, thus the showing is insufficient to overcome the prima facie case of obviousness. Attention is directed to MPEP § 716.

Thus, in view of the foregoing the examiner maintains the positions set forth in the Final Office Action.

/Saira Haider/  
Examiner, Art Unit 1796